CLIA UPDATE

Judith A. Yost
Director, Division of Laboratories

STATUS

- Waived Lab Survey Project
- 2001 Lab Registry
- New & Improved CLIA Website
- Rapid HIV CLIA Categorization
- DOD Lab Program Re-Approval & MOU
- Secretary's Regulatory Reform Initiative
- Final QC Regulation Clearance
- DAB/ALJ Hearing Master Index
- Criteria for Test Waiver Final Regulation

CLIA Statistics April 2002

Total Laboratories Enrolled	175, 401
-Certificate of Compliance	21, 622(13%)
-Certificate of Waiver	94,012(55%)
-Certificate of PPM	37,915(22%)
-Certificate of Accreditation	16,308(10%)

Exempt State Labs	5499
-New York (Except POL's)	2772
-Washington	2772

CLIA Authority

- CMS has delegated authority for all CLIA regulations.
- CMS is working with Tri-Agencies to coordinate program policies & priorities.
- Regular Tri-Agency meetings are being convened.
- Progress has been made, communication enhanced & mutual priorities determined.

Waived Lab Project

- Studies by CMS & others indicated 50% of waived labs have quality problems.
  - Not following mfgrs.' instructions; not doing QC.
- Followup data of problem labs reflects compliance is maintained 75% of time using education.
- CMS compiling "Clearinghouse" of existing educational programs for CLIA Website.
- CMS initiated surveys of 2% of waived labs annually for 3 years in all states Apr. 15, 2002.
  - Comprehensive information collection including "outcomes".

Waived Lab Project Cont'd.

- CMS working with manufacturers to enhance clarity of instructions.
- CMS, FDA & manufacturers on NCCLS workgroup to develop international labeling standards.
- Tri-Agencies working on final rule for waived criteria.
- CMS will evaluate survey findings annually & at 3 yrs. to determine appropriate oversight of waived labs.

2001 Lab Registry

- Can be found on CLIA web site.
- Lists 221 labs with sanctions completed.
  - 196 individual labs; some listed twice.
- Reflects more labs than previously(207); includes *repeat* offenders.
- Incorporates labs from exempt states, OIG & accrediting organizations in eight categories.

Successes

- Hearing Decisions Web Index
- CLIA Website Transition
- Department of Defense (DOD) MOU

Hearing Decision Master Index

- Decision, Synopsis, Summary Points.
- Basis for Sanctions.
- Arguments by both sides of case.
- Excerpts from the ruling & referenced cases.
- Complete actual hearing decision, applicable regulatory references.
- Updated annually.
- CLIA Web site: www.cms.hhs.gov/clia/hearinggroup.asp.
- ***CLIA has never lost a case!!***

www.cms.hhs.gov/clia/

- News
- Special Alerts
- How to Apply
- Program Description/Projects

- Regulations & Federal Register Documents
- Test Categorizations
- Fee Schedule
- State Agency Contacts
- CMS Regional Office Contacts

www.cms.hhs.gov/clia/ (Cont)

- Approved Accrediting Organizations
- Exempt States
- State Lab Licensure Programs
- PT Providers
- Certification Boards
- FAQs
- Statistics
- Hearing Decisions
- Lab Registries
- Medicaid CLIA Releases
- OIG Reports

DOD Re-Approval

- Secretary DHHS & Secretary DOD MOU for approval of DOD lab oversight program.
  - AFIP works with DOD on standards.
  - Extended for 5 years.
- Most DOD labs accredited by CAP.
- DOD regulations are equivalent to CLIA.
- DOD labs may have unusual circumstances.

To Be Announced

- Secretary's Regulatory Reform Initiative
- Rapid HIV Test Categorization Status
- Final QC Regulation
- Waived Test Criteria Final Regulation

Regulatory Reform Initiative Draft Recommendations (1)

- Simplify/clarify regulations.
- Provide information to POLs about training opportunities.
- Update website/ possible link to NLTN.
- Develop & disseminate basic laboratory practices document.
- Offer technical assistance in interpreting reg requirements.
- Modify the AQAS as an educational tool.

Regulatory Reform Initiative Draft Recommendations (2)

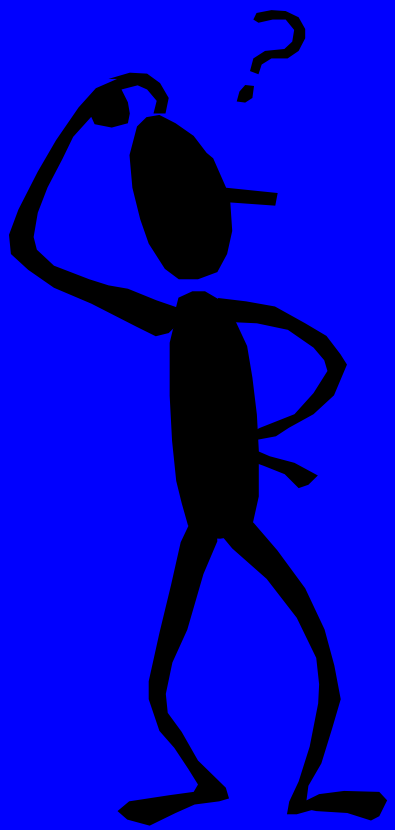
- Increase the number of POL reps on CLIAC.
- Conduct training at industry meetings.
- Design educational brochure for POLs.
- Solicit feedback at Open Forums.
- Place education clearinghouse on CLIA website.
- Promote self assessment tools for laboratories.

Final QC Regulation

- Finalizes QC, PTM & QA—due end 2002.
  - Most standards unchanged.
- Closes phase-ins that expire 12/31/2002.
  - Ph.D lab dir.; mod. comp. QC; FDA role.
- Reflects new technology; responds to comments.
- Incorporates basic Quality Systems concepts & CLIAC recommendations.
  - Follows lab workflow/prevents errors.
- Streamlines, simplifies & adds QC flexibility.
- Has 90 day effective date to educate & implement.
  - Guidance will be forthcoming.

Waived Test Criteria Regulation

- Revised criteria published by FDA in draft guidance to be withdrawn.
- FDA now using ’95 proposed rule used by CDC for waiver reviews.
- Final rule including comments under development by Tri-Agencies.
- *Issue 1:* Movement to waive rapid HIV test.
  - Pre & post analytical considerations.
  - PACHA meeting conclusions.
- *Issue 2:* QC for waived tests—recommended or required when no failsafe is present.



THE END!!

THANK YOU!!

Questions???